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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/469,606	12/22/1999	HEINZ PETER VOLLMERS	50072/002002	5150

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CLARK & ELBING LLP  
101 FEDERAL STREET  
BOSTON, MA 02110

EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1643

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07/25/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/469,606	<b>Applicant(s)</b> VOLLMERS ET AL.	
	<b>Examiner</b> Alana M. Harris, Ph.D.	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1, 4, 42, 43 and 45-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 42, 43 and 45-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date. _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Arguments***

1. Claims 1, 4, 42, 43 and 45-56 are pending.

Claims 1, 4, 42, 43 and 45-56 are examined on the merits.

### ***Maintained Grounds of Rejection***

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The rejection of claims 1, 4, 42, 43 and 45-56 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

Applicants reiterate in the Remarks submitted April 30, 2007 beginning on page 2 the claimed invention complies with the written description requirement of 35 USC § 112, first paragraph. Applicants also recapitulate the Court's decision regarding *Enzo Biochem* setting forth supposed differences between the said case and their instant claimed invention. Applicants argue "[t]he Office fails to provide any reason as to how the [claimed invention] is distinguished from that of *Enzo Biochem*.", see page 4 of Remarks. Applicants' arguments filed April 30, 2007 have been fully considered, but they are not persuasive.

Applicants are aware that compliance with the written description requirement is not based alone on "a showing of possession alone does not cure the lack of written

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description." *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956, 969-70, 63 USPQ2d 1609, 1617 (Fed. Cir. 2002). Applicants' specification does not provide relevant identifying characteristics and details on the tumor-specific N-linked glycostructure listed in the claims. It remains unclear what the structure is of the tumor-specific N-linked glycostructure. Location of the single N-linked glycosylation site on CD55 is not the same as knowing the structure.

In view of Applicants not being able to define, nor characterize the glycostructure, one of ordinary skill in the art is not clear on the variability that possibly exists within the genus of glycoproteins. For the reasons of record and the established analysis provided in previous Actions there is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645 and the rejection is maintained.

#### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. The rejection of claims 1, 4, 42, 43 and 45-56 under 35 U.S.C. 102(b) as being anticipated by Vollmers et al. (Cancer 76(4): 550-558, August 15, 1995/ IDS reference

submitted January 26, 2004), as evidenced by Hensel et al. (Cancer Research 59: 5299-5306, October 15, 1999/ IDS reference submitted January 4, 2002) is maintained.

Applicants assert their Results section found in the specification on page 28 provides evidence the claimed invention, an isolated glycoprotein was isolated implementing specific conditions that are remiss from Vollmers' preparations, see bridging paragraph of pages 6 and 7 within the Remarks submitted April 30, 2007. Applicants do submit Hensel uses the same membrane preparations of 23132 cells as they do, however Vollmers does not describe said preparations of the 23132 cell extract. Applicants' points of view and arguments have been carefully considered, but found unpersuasive.

Vollmers discloses the same tumor cell line, 23132 (stomach carcinoma) as Applicants, see page 553, Figure 2 and column 2, In vivo...section. This cell line inherently has a glycoprotein comprising the human amino acid primary structure of CD55 and a tumor-specific N-linked glycostructure and exhibits and possesses the same properties as that claimed. This disclosed cell line comprises the said structure and glycostructure with a relative molecular mass of approximately 82kDa as evidenced by Hensel. Hensel is extrinsic evidence that shows the 23132 cell extract of Vollmers is the same as Hensel's and inherently contains the same glycoprotein of about 82kDa, see Vollmers page 552, Western Blots sections and Hensel, page 5300, first column, Purification... section. The date of Hensel as indicated by Applicants is after the priority date of the present application, however the date of this extrinsic evidence is moot. Applicants are requested to review the MPEP 2124, particularly section III, wherein

Also note that the critical date of extrinsic evidence showing a universal fact need not antedate the filing date. See MPEP § 2124.

Hence, the rejection is proper and maintained for the reasons stated and of record.

### ***Conclusion***

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**ALANA M. HARRIS, PH.D.**

**PRIMARY EXAMINER**



Alana M. Harris, Ph.D.  
12 June 2007